App. No.: 10/809,761 Docket No.: 31175413-004002 Amdt, dated June 23, 2006 (PATENT)

Reply to Office Action mailed March 23, 2006

REMARKS/ARGUMENTS

Interview Summary

Applicant appreciates the Examiner's Interview granted on March 6, 2006. The Examiner stated that Claim 17 was directed to DNA and either the Applicant accepts withdrawal of the claim or a formal restriction would be mailed. The Applicant respectfully traverses the Examiner's restriction requirement. Claim 17 was directed to nucleotides encoding the protein of SEQ ID NO.: 8. One method of administering the protein of SEQ ID NO.: 8 was through administration of DNA encoding the protein of SEQ ID NO.: 8. A search of the protein of SEQ ID NO.: 8 and DNA encoding the protein of SEQ ID NO.: 8 would be coextensive and present no additional burden to the Examiner. In order to expedite prosecution of the application, the Examiner has withdrawn claim 17. The Applicant reserves the right to pursue DNA encoding the protein of SEQ ID NO.: 8 in a subsequent application.

Correction of Inventorship 35 U.S.C. §1.48(b)

Dr. A. Yousif Shamoo is to be deleted as an inventor of the present application. Please see the attached statement prepared in accordance with 35 U.S.C. §1.48(b).

Nonprovisional application-fewer inventors due to amendment or cancellation of claims. If the correct inventors are named in a nonprovisional application, and the prosecution of the nonprovisional application results in the amendment or cancellation of claims so that fewer than all of the currently named inventors are the actual inventors of the invention being claimed in the nonprovisional application, an amendment must be filled requesting deletion of the name or names of the person or persons who are not inventors of the invention being claimed. Amendment of the inventorship requires:

- (1) A request, signed by a party set forth in § 1.33(b) [patent attorney/agent, assignee, or applicants], to correct the inventorship that identifies the named inventor or inventors being deleted and acknowledges that the inventor's invention is no longer being claimed in the nonprovisional application; and
- (2) The processing fee set forth in § 1.17(i) [\$130.00 for correcting inventorship].

Dr. Shamoo is being deleted as an inventor because claims 1-10, 18, and 21 have been canceled. Dr. Shamoo was a joint inventor on one or more of the canceled claims but is not an inventor of currently pending claims 11-15, 19, 20, or 22-24.

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Elected subject matter

Applicant has elected to pursue claims directed to SEQ ID NO.: 8. All of the currently

pending claims are directed to a method of inhibiting a bacterial infection by administering a protein of SEO ID NO.: 8 or combinations of proteins including SEO ID NO.: 8. If methods of

treatment using the protein of SEQ ID NO.:8 are novel, combinations including SEQ ID NO.: 8,

more specifically combinations of SEQ ID NO.: 8, 14, & 15, are also novel.

Enablement

Claims 4-5 and 8 were rejected under 35 U.S.C. §112 as not enabled and not described.

The Examiner contends that the antibacterial proteins could not find a bacterial cell nor traverse

the bacterial membrane. Applicant respectfully disagrees.

Multiple delivery means are available, including noninvasive means like topical

application, oral administration, and inhalation. The specification identifies several means of delivering the peptides to the bacteria including direct *in vivo* delivery of an antimicrobial protein

or indirectly delivered by a bacteriophage that encodes said protein (¶19). "[T]he proteins could

be used to treat such infections directly topical," as stated in ¶92. The specification does

2. The specification does

describe multiple delivery techniques.

Applicant kindly reminds the Examiner that traversing a bacterial membrane is not the

same as traversing eukaryotic membranes, the phage proteins naturally traverse bacterial cytoplasm, and the bacterial DNA is contained within the cytoplasm. The bacteria does not have

a nucleus thus no nuclear membrane must be traversed. Weiss, et al. describe a method of

improving oral absorption of antibiotic molecules by making the molecule mimic proteins.

Proteins are naturally absorbed in the human/mouse gut and the modification Weiss makes to the

antibiotic molecule are attempts to mimic proteins. Weiss specifically states, "Amino acid

prodrugs of the THF carbapenems were synthesized with the aim of increasing the level of

absorption through the use of an active transport system such as the di- or tripeptide transport

system." (Discussion, p. 463). Thus, Weiss actually teaches that the peptides would be easier to

administer than a small molecule.

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CONCLUSION

Bacterial membranes are traversed by bacteriophage more easily than mammalian membranes, thus the peptides described, or phage encoding the peptides, need only be in the vicinity of the bacteria to traverse the bacterial membrane. Once inside the bacterial cell, the peptides naturally bind DNA. The application describes direct and indirect administration of the peptides, including topical application, oral administration, and inhalation. Although a preferred embodiment uses bacteriophage to deliver the peptides, Applicant should not be limited to a preferred embodiment as multiple delivery methods are known, described, and available to one of ordinary skill in the art.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue. The Applicant respectfully requests the Examiner contact them if there are any questions or procedures that need to be addressed. No fees are believed to be due for this submission. However, should there be any additional fees required, please charge such additional fees to Deposit Account No. 50-3420, under Order No. 31175413-004002 (MDB).

Dated: June 23, 2006 Respectfully submitted,

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